



Marine Genetic Resources Beyond National Jurisdiction: Elements of a New International Legally Binding Instrument

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Marine Genetic Resources Beyond National Jurisdiction:

Elements of a New International Legally Binding Instrument

This note is intended to inform country representatives, negotiators, and legal and technical advisers of springboards and roadblocks to an acceptable international legally binding instrument on the conservation and sustainable use of marine biodiversity of areas beyond national jurisdiction under UNGA resolution 69/292.¹

Biodiversity of areas beyond national jurisdictions (ABNJ) is the last global commons, and technological developments mean that it is ripe for harvesting. The principle of freedom of the seas, and the freedom of states to conduct scientific research under the UN Convention of the Law of the Sea (UNCLOS), makes the need for a global governance regime that is fair, informed and progressive an urgent one. This briefing note is based on a full paper available on SSRN.²

1. Common Heritage of Humanity

The central issue for any new international legally binding legal instrument on biodiversity beyond national jurisdiction (BBNJ) is the normative basis of the instrument that can guide scope of application, interpretation and enforcement. While 'mineral resources', covered in Part XI of UNCLOS, do not include marine genetic resources (MGR) and the area of the deep-sea floor, it can be argued that its ecosystems, biodiversity and thus MGR are within the purview of the common heritage of humanity principle (CHH), though various parties have chosen not to pursue this legal debate.³

There are three possible approaches:

1. MGR in areas beyond national jurisdictions can be subjected to the principle of common heritage of humanity either as communal ownership or as joint management of global commons.
2. MGR is not subjected to the principle of CHH.
3. The issue of what to do with MGR outside territorial waters is not addressed.⁴

No treaty can account for all aspects of an emerging technological area without a jurisprudential basis. To allow for principled growth of legal rules and avoid a normatively incoherent approach, CHH must apply to biodiversity in areas beyond national jurisdictions in some form.

Resolve: Whether the common heritage of humanity principle applies to the ownership of biodiversity including marine genetic resources in areas beyond national jurisdiction or only (or at least) to a joint management regime over global commons of which marine genetic resources are a part.

1 UNGA 69/292 (6 July 2015) Development of an international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. Available here <<https://documents-dds-ny.un.org/doc/UNDOC/GEN/N15/187/55/PDF/N1518755.pdf?OpenElement>> This note is a response to the *Mare Geneticum* framework discussed at Aberdeen University, June 27–28 2018. A Brogiato et al., 'Mare Geneticum: Balancing the Governance of Marine Genetic Resources in International Waters' 2017. Available here <http://booksandjournals.brillonline.com/content/journals/10.1163/15718085-13310030>

2 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3215356

3 M Bourrel, T Thiele, D Currie 'The Common Heritage of Mankind as a Means to Assess And Advance Equity in Deep Sea Mining' *Marine Policy* 2016. Available here <<http://www.lse.ac.uk/iga/assets/documents/publications/2017/common-of-heritage-of-mankind-deep-sea-mining.pdf>>

4 The European Union is for instance, proposing a pragmatic approach that does not discuss this legal base. Development of an International Legally Binding Instrument under UNCLOS on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Process): EU and Member States Position Paper 22 Feb 2017. Available here http://www.un.org/depts/los/biodiversity/prepcom_files/rolling_comp/EU_Written_Submission_on_Marine_Genetic_Resources.pdf

2. The Legal Status of Access

Any binding international legal instrument must recognise and define 'access' to marine genetic resources beyond national jurisdiction and imbue the act with any rights and obligations of benefit-sharing that attach under the instrument. Access is the pivotal act which ignites the value chain of that genetic resource, and also identifies where a particular resource has been acquired. Without access there cannot be utilisation, including commercialisation. In order to exercise due diligence in acquisition of genetic resources, access would have to be traceable in some form, at least to prove that it was not acquired in territorial waters and is not under the purview of the Nagoya Protocol.⁵ It is also important to move away from the loopholes and structural problems related to implementation and access to ex situ collections⁶ that follow from the ambiguity in the Nagoya Protocol with respect to access and utilisation.⁷

Resolve: Any binding international instrument must recognise and define 'access' to marine genetic resources of areas national jurisdiction and specify the rights and obligations of benefit-sharing in relation to access as well as use.

3. The Access Gap

A recent study has detailed how 98 per cent of 1,600 gene sequences associated with species found in deep-sea and hydrothermal vents are owned by actors located or headquartered in only 10 countries.⁸ In terms of negotiations, the inability of the vast majority of countries to engage in deep-sea expeditions is likely to be accompanied by a fear of losing out on bio-scientific and commercial gains. There is much in the recent history of biotechnology that justifies this fear – including private appropriation of human genetic resources through patents despite the UNESCO Declaration denoting the human

genome as common heritage of humanity.⁹ It is because of the reality of and likely entrenched nature of technical barriers that the legal status of access of MGR becomes paramount. If we do not imbue the act of access with legal status to which obligations are attached, it would amount to little more than a technical and scientific might is right¹⁰ approach when it comes to appropriating marine genetic resources beyond national jurisdictions.

Resolve: Technical barriers and the access gap should not be allowed to downplay the commercial and technical prospects of marine genetic resources accessed from areas beyond national jurisdictions. As long as some can access such marine genetic resources, the communal nature of such resources remains under threat.

4. Notification/Registration or Authorisation

Art 138 of UNCLOS requires international cooperation and mutual understanding. Currently due to the principle of freedom of the high seas it is legal to access marine genetic resources, and there are indications that research activity on the high seas is ongoing.¹¹ Registration of who is accessing biodiversity will facilitate co-operation and mutual understanding of how marine genetic resources are being handled. Such registration could involve either 'notification' or a more consequential 'authorisation' regime.

A notification approach would require researchers to inform a transnational authority of intention to conduct sampling expeditions.

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- 5 The Nagoya Protocol, a supplementary instrument of international law under the Convention on Biological Diversity (CBD), does not define access, but allows it to be treated differently from utilisation of genetic resources. Under EUR 511/2014 implementing it, benefit-sharing obligations are triggered by use rather than access
 - 6 F Rabitz, 'Biopiracy after the Nagoya Protocol: Problem Structure, Regime Design and Implementation Challenges' *J of the Brazilian Political Science Organization* 2015 9 (2) 30-53. Available here <http://www.scielo.br/pdf/bpsr/v9n2/1981-3821:bpsr-9-2-0030.pdf>
 - 7 'The Two Worlds of Nagoya: ABS Legislation in the EU and Provider Countries: Discrepancies and How to Deal with Them' *Natural Justice/Public Eye Report* Dec 2016
 - 8 R Blasiak et al., 'Corporate Control and Global Governance of Marine Genetic Resources' *Science Advances* 6 June 2018. Available here <http://advances.sciencemag.org/content/4/6/eaar5237> Also see National Institute of Genetics (2015). Access to Marine Genetic Resources and Benefit-sharing from Their Academic Use, Report of MGR Workshop in Japan (edited by H Morioka), Tokyo, available from http://nig-chizai.sakura.ne.jp/abs_tft/wpcontent/uploads/2016/08/Marine-genetic-resources.pdf as cited in Carlos Correa, *Access to and Benefit-Sharing of Marine Genetic Resources Beyond National Jurisdiction: Developing a New Legally Binding Instrument* South Centre Research Paper 79 (September 2017) p 6
 - 9 1997 UNESCO Universal Declaration on the Human Genome and Human Rights. See LS Cahill, 'Genetics, Commodification, and Social Justice in the Globalization Era' 2001 *Kennedy Inst of Ethics J* 11 (3) 221-38 Available here <https://www.ncbi.nlm.nih.gov/pubmed/11700680>
 - 10 Referred to as a first-come-first-served rule under the principle of freedom in the high seas in the National Institute of Genetics (2015) report n 8 above
 - 11 See discussion in C Correa South Centre Report n 8 above

Although there would be no authority to prevent scientific exploration,¹² there are multiple advantages of such a registration system:

1. To enable 'conservation and sustainable use' under UNGA resolution 69/292
2. To enable and ensure possibility of benefit-sharing.
3. Facilitate due diligence and corporate social responsibility with respect to sampling and use of resources. Here it is worth noting that agreeing on the CHH principle would strengthen the basis of social responsibility by corporations and other entities.

Realistically, a notification regime would be easier to achieve than an authorisation framework, as the latter would need to invest authority in an international organisation, which would administer or hand out the authorisations based on certain prior agreed conditions.

Resolve: Registering scientific expeditions on the high seas either through notification or authorisation is a necessary, although not sufficient, component of the management of biodiversity in areas beyond national jurisdictions.

5. Binaries of Commercial/Non-Commercial and Academic/non-Academic

Traditionally, academic research has been associated with non-commercial activity and has benefited from certain privileges.¹³ In recent years, the boundaries between academic and commercial research have become blurred¹⁴ and the association of academic with non-commercial activity no longer reflects reality.

Most universities now insist on patents being sought for research results across the board, even prioritising patents over possible publications.¹⁵ Patent law facilitates this by operating low thresholds for inventions including for those derived bioinformatically.¹⁶ Any analyses of patents as an indication of commercial activity could also be misleading for many different reasons. While no one ought to take a patent as a definite commercial prospect, everyone knows it is a good signal of probable value;¹⁷ conversely, the lack of a patent does not indicate solely non-commercial motives.¹⁸

Researchers often move between universities and the commercial sector.¹⁹ We also see corporations populating and maintaining public repositories or libraries of genetic information. The giving away of information can preempt appropriation from competitors or move the level of innovation forward, benefiting the long-term interest of the commercial entities concerned.²⁰

Resolve: Labels such as academic/non-commercial, and commercial/non-academic must not be used to justify good faith advantages. All research entities are a complex mix of self and public interest in different proportion, expressed through a range of measures such as publications and patents. Focus instead on and reward the nature of the research, ability and explicit intention to participate in open-science initiatives and academic norms of sharing.

6. Patents and MGR in Areas Beyond National Jurisdictions

Most of the world has signed up to the TRIPS agreement, under which countries are obligated to implement national patent laws at a high level of harmonisation.²¹

12 Arts 256 and 257 of UNCLOS give all states the 'right to conduct marine scientific research'.

13 Through, for instance, the protocol's recommendation to promote non-commercial research in Art 8 and *Mare Geneticum* framework n 1 above p 17

14 See, for instance, M Haas & S Park, 'To Share or Not to Share? Professional Norms, Reference Groups, and Information Withholding Among Life Scientists' 2010 *Organization Science*, 21 (4), 873-891

15 R Eisenberg and M Heller, 'Can Patents Deter Innovation? The Anticommons in Biomedical Innovation' *Science* 280 (5364) May 1 1998 pp. 698-701

16 See, for instance, *HGS v Eli Lilly* [2011] UKSC 51, *Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology* UNEP/CBD/WG-ABS/3/INF/411 January 2005, S Thambisetty 'Learning Needs of the Patent System and Emerging Technologies: A Focus on Synthetic Biology' (2014) IPQ 13

17 M Lemley and C Shapiro, 'Probabilistic Patents' 19(2) *J of Econ Perspectives* 75-98 (2005)

18 Encouraging more SMEs to patent is one of the stated aims of the push to establish the Unitary Patent Court in Europe <https://www.epo.org/news-issues/news/2018/20180416b.html>

19 S Thambisetty, 'Patents as Credence Goods' 2007 *Oxford J of Legal Stud* 27(4) 707-740

20 R Merges, 'A New Dynamism in the Public Domain' 2004 (71) *Uni of Chi LR* 183-203

21 Trade Related Intellectual Property Rights Agreement. J Duffy 'Harmony and Diversity in Global Patent Law' 2002 Faculty Publications. Paper 849. <http://scholarship.law.wm.edu/facpubs/849>; see also P Drahos, 'Trust Me: Patent Offices in Developing Countries' *American Journal of Law and Medicine* 2008 (34) 151-174

Most jurisdictions allow patents on genetic material and data. This includes material developed from biodiversity samples taken from the high seas. Under the isolation test in patent law, genetic material may be patented simply by being accessed, characterised and otherwise made available in a form that does not exist in nature. This is a low novelty threshold and makes genetic material open to patents widely.²²

The amount of genetic data available online and in repositories makes it difficult for patent examiners to verify novelty.²³ Hence genetic material in the public domain can provide private entities with an enormous competitive and commercial advantage and end up being patented. Moreover, location of a gene sequence within a gene bank in the absence of a known probe is in fact regarded as a biochemical process, similar to the isolation of a component from nature that lends patentability to gene sequences.²⁴

There are indications that commercial entities are patenting marine genetic resources from areas beyond national borders in substantial numbers.²⁵ Scientific innovations including pharmaceuticals developed from these patented genetic resources will almost certainly be inaccessible to poorer populations. Privately owned patents on genetic material and information, in the absence of overarching legally binding principles, are not compatible with the idea of good governance of MGR from areas beyond national jurisdiction in the best interests of all mankind. It is true that an international forum such as the WIPO is more specialised but due to a phenomenon called 'regime shifting' in the international intellectual property system, the terms in which patents and other intellectual property rights are referenced in the biodiversity beyond national jurisdictions (BBNJ) process can have a robust impact on how this issue is taken up at the WIPO.²⁶

Resolve: The BBNJ process needs to address the question of intellectual property rights. It needs to recognise that the acquisition of privately owned patents is already possible and that this is potentially incompatible with the fair, equitable and sustainable use of marine genetic resources from areas beyond national jurisdiction. Only by allowing genetic resources to be identified as such can the relevance of biodiversity beyond national jurisdictions be maintained.

7. Track and Trace: Scientific and Legal Imperative

Track and trace attached to notification or authorisation is necessary to enable scientific accountability as well as to actualise any forthcoming benefit-sharing. Without such track and trace there would be no way to link any future actions related to MGR to conservation, sustainable use or benefit-sharing.

First and foremost, any track and trace system must resolve the position of *ex situ* and *in silico*²⁷ genetic resources.²⁸ Not to do so runs the risk of making this treaty obsolete even before it begins. Track and trace for MGR beyond national jurisdiction is likely necessitated by the implementation of the Nagoya Protocol. In fact – at least within the European Union – due diligence requirements mean that collections ought to obtain and keep information about the provenance of material and data they hold.

Secondly, any track and trace system should interact with the patent system. Intellectual property rights amount to legal track and trace.²⁹ In order to make any sort of monetary benefit-sharing possible, unless provenance of the genetic resource can be identified in the patent, there is no way to enforce or monitor benefit-sharing. This will pave the way for contractual avoidance in individual transactions or contracts, which currently is of acute concern under the Nagoya Protocol.

22 The US Supreme Court in *AMP v Myriad* 569 US 576 disallowed patents on genomic DNA, but allowed claims on cDNA, which is exceptionally easy to derive from genomic DNA. The decision does not therefore amount to a dramatic change in how business around genetic material is conducted. S Thambisetty, 'Alice and Something More: The Drift Towards European Patent Jurisprudence' 2016 *J Law and Bioscience* 691-696 and also see similar decision in *D'Arch v Myriad Genetics Inc* [2015] HCA 35

23 See O Jefferson et al., 'Public Disclosure of Biological Sequences in Global Patent Practice' 2015 *World Patent Information* <https://doi.org/10.1016/j.wpi.2015.08.005>

24 P Cole, 'Patentability of Genes: A European Union Perspective' *Cold Spring Harb Perspect Med* 2015 May 5(5)

25 R Blasiak et al., n 8 above

26 L Helfer, 'Regime Shifting in the International Intellectual Property System' *Perspectives on Politics* 7(1) 39-44

27 Ad Hoc Technical Group (AHTG) on Digital Sequence Information on Genetic Resources serving the needs of the Nagoya Protocol under the CBD. <https://www.cbd.int/abs/dsi-gr/ahteg.shtml>

28 Such as the Obligatory Prior Electronic Notification (OPEN) in *Mare Geneticum* framework n 1 above

29 Although a few countries have done so already, the Nagoya Protocol does not institute a declaration of origin for all genetic resources in patent applications. In the following list not all of the requirements are in prejudice to the processing of patent applications or right granted http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf

This problem can be sidestepped in the BBNJ process by hooking the question of provenance to the patent system. This will bolster the structural weakness related to the ambiguity of using bilateral contracts to enforce normative objectives of international law.³⁰ Such a declaration on provenance is not an onerous process, and can potentially be absorbed in the bibliographic information routinely submitted as part of the patent examination process. Given the logical need it fulfils, and the ease with which it can potentially be instituted, the only reason not to implement this measure is to deny any possibility of monetary benefits being shared.

Resolve: Any track and trace method must be both technical and legal. Declaration of provenance of marine genetic resources (whether in situ, ex situ and in silico) from areas beyond national jurisdiction is essential to ensure monetary benefit-sharing. If the BBNJ process does not explicitly refer to patent rights, it will not be able to ensure fair and sustainable use of a global commons.

8. Embargoes and Exclusivity

It has been suggested that any researcher who accesses MGR beyond national jurisdictions must be entitled to a period of embargo over the results of that sampling exercise.³¹ During this period there would be no obligation to publish information on what was sampled, allowing the researchers to work on either publications or patents without fear of being gazumped. It protects the investment of time, effort and money, which could be seen as desirable to incentivise researchers.

A note of caution and explanation is warranted here. If research expeditions are resource and technology intensive, then the very fact that the samples were acquired and are in the possession of the research crew provides an invaluable lead-mover advantage that would be difficult to overcome. An embargo will entrench the lead-mover advantage, enabling extraction of value both through publications and patents without fear of competition, functioning essentially like an intellectual property right.

There is often a chain-reaction dynamic associated with property – property begets property. Introducing

new property or property-like rights in a hitherto un-propertyised environment often leads to demands for second-generation property rights that do not have anything to do with efficiency calculations. The lead movers can play an underestimated role in triggering this increased propertyisation.³²

Resolve: Embargoes and exclusivity models should only be used where absolutely necessary, particularly where they compete with open-access intent. In the case of marine prospecting on the high seas, there is a danger of entrenching lead movers: the most technologically proficient developed countries and wealthy corporations. Existing technical barriers to entry mean that there should be no need for such embargoes.

9. The Malleable Nature of Benefit-sharing

Despite its recurrent nature and its use in medical and genetic research, international law and political philosophy benefit-sharing as a legal concept has never been satisfactorily defined.³³ Growing empirical evidence suggests that in practice ‘benefit-sharing rarely achieves its stated objectives, and may actually end up working against its purposes’ and is seen as a ‘disingenuous win-win rhetoric’ that leads to loss of control and access over resources.³⁴ References to non-monetary and monetary benefit-sharing in a new BBNJ treaty process should use international biodiversity law as a point of departure rather than a reference.

While it will not guarantee it, monetary benefit-sharing is virtually impossible without a formal link between any international legally binding treaty and the international patent system. Conversely, it would be good to acknowledge directly that one of the main reasons not to make such a link effective is to escape the burden of having to share monetary benefits.³⁵

The problem with non-monetary benefit-sharing is that since it is almost always qualitatively defined, it cannot be measured, or monitored against benchmarks. Non-monetary benefits are often couched in terms of global goods – progress of science, making knowledge available, etc.

30 T R Young and M W Tvedt, *Drafting Successful Access and Benefit-Sharing Contracts* (Brill/Nijhoff 2017) p 468

31 The *Mare Geneticum* framework suggests that the period could be extended with an exclusivity fee: n 1 above

32 S Safrin, ‘Chain Reaction: How Property Begets Property’ 2007 (82) *Notre Dame Law Rev* 1917

33 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2652775/>

34 E Morgera, ‘An International Legal Concept of Fair and Equitable Benefit-Sharing’ University of Edinburgh School of Law Research Paper Series No 2015/20 at p 3

35 According to some reports, China has refused to participate in monetary benefit-sharing as they already expect to be net providers rather than net recipients (Aberdeen Workshop discussion, n 1 above)

However, like technology transfer,³⁶ such amorphous benefits remain platitudinous in the absence of requisite technical skill in local or regional communities.

In terms of benefit-sharing, as 'local' communities do not exist in the ABNJ context, the process must establish a new concept of regional stewardship. In terms of non-monetary benefits, the establishment of linked technical universities to be housed in the southern hemisphere, funded by contribution funds and capable of improving capacity for marine prospecting, would be meaningful.

Resolve: Declaration of provenance in patent applications for marine genetic resources beyond national jurisdictions is a necessary condition for any monetary benefits to be shared. Non-monetary benefits must be supported by tangible, measurable aspects and overseen by regional stewardship.

10. Status and Content of Open-Access

Open-access initiatives as part of the public goods framework are often offered up as a tangible benefit of scientific research and exploration, as in the *Mare Geneticum* framework.³⁷ There are at least three concerns here: first is the relationship between open access and any demands for embargoes or exclusivity. We can expect that during the embargo, much of the valuable information will be published, enclosed in a patent application or amount to commercially sensitive information that cannot be shared. A full open-access model would therefore be less meaningful if it competes with an embargo.

Secondly, open-access can often be detrimental to the free availability of information because it does not prevent others from capturing openly available information in private databases or patents. The only way to prevent this would be to adopt a non-exclusive licensing model where the genetic resource is already under some property arrangement such as a patent and it is then made available for all to use, non-exclusively. This sort of arrangement is sometimes referred to as open-patenting.³⁸ In case of a merging of open-access and commercial genetic resources, it would be equitable for the commercial information to also become openly available rather than the reverse. This would be much more difficult to police, but could be done with political will and robust track and trace methods.

Third, talk of open-access often misses a crucial element of transparency, and that is to consider the status of commercially sensitive information. Both commercial and academic entities are often reluctant to make available contractual information or licensing terms, choosing instead to cover them under the umbrella term of 'commercially sensitive'. This is a particularly difficult barrier to overcome in the case of monetary benefits. Any open-access initiative should include not just genetic resources but also commercial and transactional information around that genetic resource, if benefits-sharing is to be monitored and good practice built up.

Resolve: There are many perils in the open-access model. The relationship with embargoes, patents and commercially sensitive information must be resolved. Open-access status of genetic resources, unless well defined, will remain difficult to police and liable to private acquisitions.

36 See calls for a new international model to make technology transfer in the context of the TRIPS Agreement Art 66.2 effective. M Shugurov, 'TRIPS Agreement, International Technology Transfer and least Developed Countries' *Journal of Advocacy, Research and Education* 2015 (2) Is. 1 74-85

37 *Mare Geneticum* n 1 above p 18

38 See M Maggiolino, 'Standardised Terms and Conditions for Open Patenting' 2003 (4) *Minnesota J of Law, Science and Technology* 785-816



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